MICROLINE SURGICAL

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K122086

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510(k) Summary

Contact Person: Dean Ciporkin, Sr. Director of Regulatory Affairs and Quality Assurance

Submitted By: Microline Surgical
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AUG 23 2012

Common Name: Electrosurgical System

Device Product Code: GEI

Classification Name: Electrosurgical Cutting and Coagulation Device and accessories
21 CFR § 787.4400

Device Panel: General Surgery/Restorative Devices

Date Prepared: August 17, 2012

Proprietary Name: MiSeal™ Reposable Thermal Ligating Shears

Device Classification: Class II

Predicate Device: This product is similar in design, composition, and function to the:
Starion Instruments Thermal Ligating Shears (K062257) cleared October 10, 2006

Establishment Registration Number: 1223422

Device description and technological Characteristics:

The MiSeal Reposable Thermal Ligating Shears system consists of the following:

MiSeal Reusable Handpiece
MiSeal Thermal Ligating Shears Kit
Universal Power Supply 200-006R

The MiSeal Reposable Thermal Ligating Shears are designed to provide thermal ligation and division in various surgical procedures. The MiSeal Reposable Thermal Ligating Shears consist of a reusable handpiece with a disposable tip. The device has heating elements at the distal tip which are activated by a finger switch located on

the handpiece of the device. The MiSeal Reposable Thermal Ligating Shears are designed to allow the surgeon control of the heating element power of the device in order to accommodate the individual patient anatomy. An instrument cord connects the handpiece to the dedicated Microline Surgical Universal Power Supply K070871.

The MiSeal Reposable Handpiece is supplied non-sterile in a foam cavity placed in a fiberboard carton and is for multiple patient uses following cleaning and steam sterilization procedures performed per the provided Instructions for Use. The handpiece can be used multiple times if cleaning and sterilization procedures are followed. The MiSeal Disposable Kit (the functional instrument Tip and power cable portion of the applied part of the system) is supplied sterile in a die-cut chipboard Packaging Insert and Tyvek/Mylar pouch and is labeled for single use only. The tip is intended to be used by a trained physician for a single patient use in open general surgery, open vascular surgery, and laparoscopic surgical procedures.

The MiSeal single use power cable is connected to the handle of the instrument handpiece and terminates at the electrical connection of the Universal Power Supply. The system power supply is supplied non-sterile for reusable use outside the sterile field.
The MiSeal device incorporates Hi and Low heating modes that are used to coagulate and cut soft tissue. The heating elements in the disposable tip are activated by a physician controlled finger switch located on the handpiece of the device. The MiSeal device is intended to provide general purpose dissection, spreading, and grasping of soft tissue during minimally invasive or open surgical procedures.

To coagulate and cut tissue, the physician grasps the desired tissue between the jaws of the MiSeal Reposable Thermal Ligating Shears and gently squeezes the thumb trigger and handpiece to close the jaws. Depressing the finger switch and squeezing the thumb trigger activates the heating elements in the distal tip. An audible low frequency tone accompanies the activation of the heating element in the variable mode to notify the physician the power is being applied. An audible high frequency tone will accompany the activation of the heating element in High power mode. Depressing the finger switch on the top of the handle provides either Hi or Low heating mode. Generally, a lower UPS output setting improves the sealing capabilities and lengthens the time required to divide tissue. Conversely, a higher output setting reduces the time to divide tissue and may result in decreased vessel seal integrity

Indications for Use:

The MiSeal Reposable Thermal Ligating Shears are intended for the simultaneous cutting and cauterization of soft tissue during surgery, and cutting of natural or synthetic, nonmetallic sutures during surgery.

Performance Testing:

Preclinical and performance tests were performed to assure the MiSeal Reposable Thermal Ligating Shears functioned as intended and met all product specifications. Sufficient data was generated and analyzed to prove that the MiSeal Reposable Thermal Ligating Shears was substantially equivalent to the predicate device.

Summary:
The information provided demonstrates that the MiSeal Reposable Thermal Ligating Shears is substantially equivalent to the Starion Instruments Thermal Ligating Shears in function, construction, intended use and indications for use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Microline Surgical
% Mr. Dean Ciporkin
Sr. Director of Regulatory Affairs and Quality Assurance
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Beverly, Massachusetts 01915

AUG 2 3 2012

Re: K122086
Trade/Device Name: MiSeal Reposable Thermal Ligating Shears
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: July 13, 2012
Received: July 16, 2012

Dear Mr. Ciporkin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K122086

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Indications for Use:

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Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R. P. Ogden mam

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K122086